

Voluntary Medical Device Manufacturing and Product Quality Program

Quality Program Pilot Framework

Public Workshop

October 10, 2017

Overview

- Pilot Governance
- Why maturity?
- Pilot goals
- Learning mindset

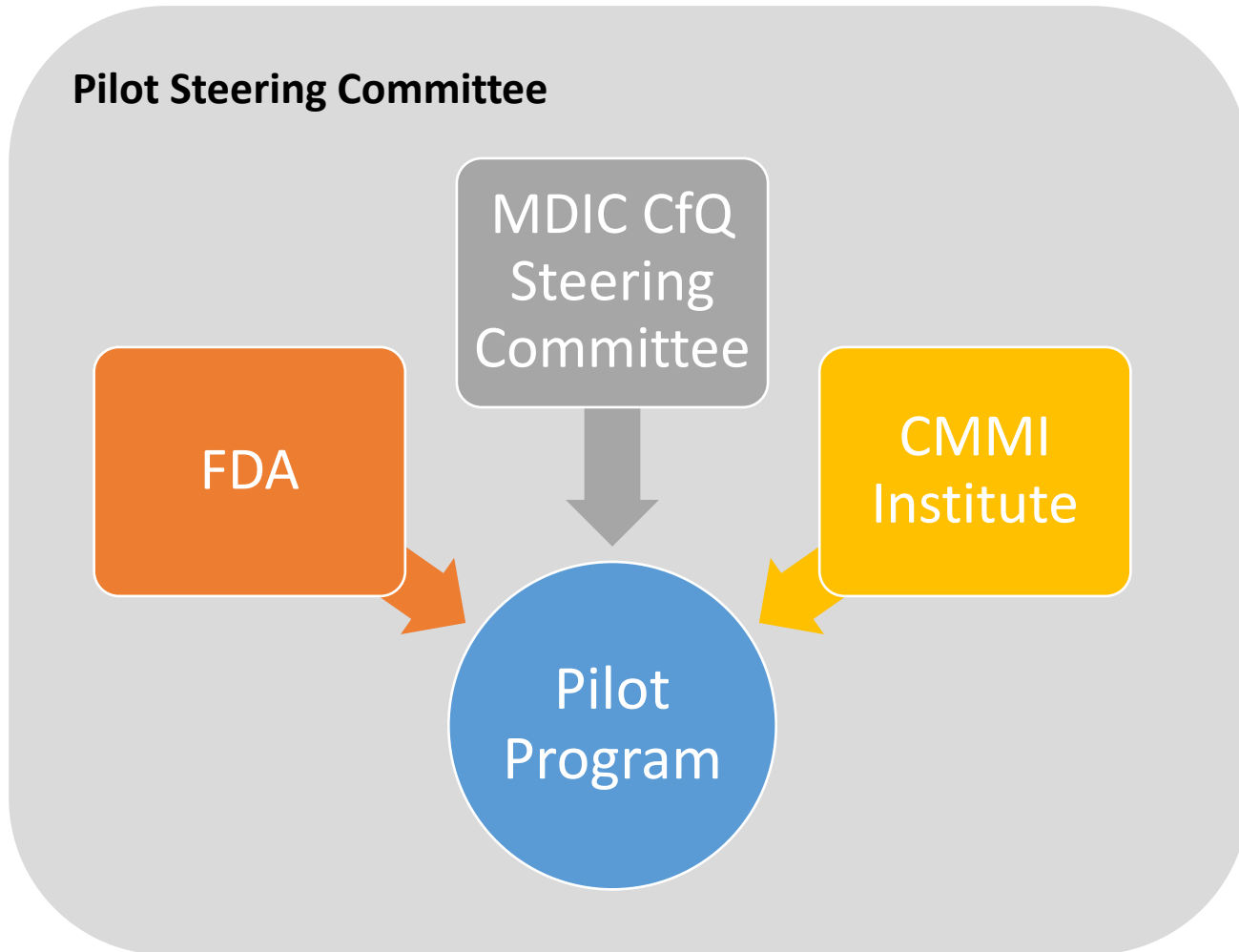


It is a pilot!

- We will not have all the answers
- We will be learning along the way
- We will be communicating and sharing
- We will be looking to drive improvement not compliance
- We are not expecting perfection, we are driving to progress and improvement



Pilot Governance



- Leadership
- Evaluates pilot progress
- Reviews and approves significant changes in direction or scope
- Serves to address appeals in cases of program de-enrollment
- Identify operational governance requirements

Pilot Steering Committee Roles and Responsibilities

FDA

- Role
 - Regulatory expertise and pilot oversight
- Responsibilities
 - Verify participant standing
 - Regulatory program modifications
 - Review and monitor appraisal summary results
 - Receive baseline effectiveness metrics
 - Receive and review effectiveness metric check-ins
 - Engage on public health and safety issues
 - Collect pilot feedback, Provide updates to the MDIC Steering Committee, and report trends or learning through pilot

MDIC CfQ Steering Committee

- Role
 - Industry and stakeholder collaboration, pilot leadership and oversight
- Responsibilities
 - Review of pilot progress and data trends
 - Leadership and direction to resolve pilot issues
 - Identify sustainable governance requirements
 - Coordinate stakeholder communication

CMMI

- Role
 - Maturity and appraisal program management and maturity model subject matter expertise
- Responsibilities
 - Manages maturity model, playbook, training, and appraiser certification
 - Manages pilot enrollment activities
 - Manages appraisal or appraiser specific issues
 - Oversight and scoping of appraisal
 - Collection of appraisal data, trending, and data summary for steering committee
 - Implements changes to pilot or appraisal based on feedback
 - Provide SME to participants and FDA

Why maturity?

- Identifying organizational capabilities and improvement opportunities
- Provide guidance of how to drive and prioritize improvements that deliver value on business objectives
- Enhance confidence, trust, and transparency

Trusted Colleagues!



Pilot goals

- Appraisal
 - Understand the scalability of the CMMI model and appraisal
 - Evaluate pilot program
 - Evaluate if pilot increases improvement efforts
- Identify objective performance metrics
 - Outcome and product quality focused
- FDA
 - Improve inspection resources
 - Improve review resources
 - Improve visibility into industry trends
 - Identify high performing firms and practices
- Industry
 - Improve resource utilization
 - Increase speed and capability to make improvements
 - Improve quality culture
 - Reduce disruption





Learning mindset

- Approach this with an open mind
- Learn what works well, what needs to improve, what is not delivering value
- Focus on adapting
- Feedback and communication

Questions?



Thank You!



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